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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/598,440

10/16/2006

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EXAMINER

FLICK, JASON E

ART UNIT

PAPER NUMBER

3763

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/598,440	Applicant(s) CARREZ ET AL.	
	Examiner JASON FLICK	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Examiner acknowledges the reply filed on 1/29/2009 in which claim 1 was amended. Currently, claims 1-11 are pending for examination in this application.

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. The term "short" in claim 11 is a relative term which renders the claim indefinite. The term "short" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

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Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-4 and 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Purdy et al. (patent number 5,215,528), in view of Rossi et al. (PGPub 2004/0243060).

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8. [Claim 1] Purdy discloses a catheter (figure 1a, item 10) with a proximal base (figure 5a, item 48), including a needle with a puncture end (figure 5a, item 15) and a cage (figure 5a), which extends the base in the proximal direction. In addition, Purdy teaches this cage forming a chamber through which the needle slides from a proximal entrance (figure 5a, item 70) to an opposite distal exit (figure 5a, item 38a).

Furthermore, Purdy discloses a sprung flexible steel blade (steel leaf spring)(figure 5a, item 58)(column 3, lines 40-43), capable of holding the puncture end of the needle in the chamber when the needle is withdrawn from the cannula, which is positioned across the chamber close to the proximal entrance of the chamber, perpendicular to the needle, and traversed by the needle. Purdy also teaches that both the needle and the blade contain structures (figure 5a, items 59 and 14c) which allow the blade at rest and freely traversed by the needle when the needle is drawn in the proximal direction.

Purdy is silent on a blade which bends and inclines the needle in order to force the needle back in the distal direction until the puncture end comes into contact against the wall. However, Rossi discloses a catheter with a blade structure which bends and applies force to a needle, thereby forcing the puncture end of the needle against the wall of the chamber (figures 1f and 2e). Purdy and Rossi are combinable because they are concerned with the same field of endeavor, namely catheters. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the structure taught by Purdy with the blade structure taught by Rossi in order to provide an alternative means of preventing the reuse of the needle.

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9. [Claim 2] Purdy and Rossi teach the limitations of claim 1, upon which claim 2 depends. In addition, Purdy discloses a perforation (figure 5a, item 59) in the flexible blade, as well as a locally modified section of the needle (figure 5a, item 14c), which prevents the needle from being withdrawn through the perforation when moved in the proximal direction. This modified section is located on the needle at a distance such that contact of the modified section with the perforation during withdrawal occurs after the puncture end of the needle is within the chamber (figure 5a).

10. [Claim 3] Purdy and Rossi teach the limitations of claim 1, upon which claim 3 depends. Purdy is silent on a chamber comprising an end wall in the distal direction containing a groove intended to contain the puncture end of a needle. However, Rossi also discloses a chamber which has an end wall in the distal direction containing a groove into which the puncture end of the inclined needle enters (figure 14d, item 10'). Purdy and Rossi are combinable because they are both concerned with the same field of endeavor, namely catheters. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the structure taught by Purdy with the groove portion of the chamber taught by Rossi in order to provide an alternative means of preventing the reuse of the needle.

11. [Claim 4] Purdy and Rossi teach the limitations of claim 1, upon which claim 4 depends. Purdy also teaches a flexible blade which constitutes a branch of a blade shaped as an L, which has a longitudinal branch (figure 5a, item 58) fixed to a longitudinal wall of the chamber and a transverse branch (figure 5a, item 60) which

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constitutes the flexible blade equipped with a perforation (figure 5a, item 59) for the passage of the needle.

12. [Claim 7] Purdy and Rossi teach the limitations of claim 1, upon which claim 7 depends. Purdy is silent on a cage which includes a nose, configured to connect with a catheter base, which is traversed longitudinally by an aperture for the passage of a needle. However, Rossi discloses the cage of the catheter including a nose (figure 14b, item 10) which slots into the catheter base (figure 14b, item 7) and which is traversed longitudinally by an aperture for the passage of the needle (figure 14b, item 1). Purdy and Rossi are combinable because they are both concerned with the same field of endeavor, namely catheters. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the structure taught by Purdy with the nose structure taught by Rossi in order to provide a means of making the injection structure detachable from the catheter base.

13. [Claim 8] Purdy and Rossi teach the limitations of claim 1, upon which claim 8 depends. Purdy also discloses the catheter needle equipped with a base (figure 5a, item 64), as well as the catheter cage including a transverse plate (figure 5a, item 60) projecting laterally, against which presses one wall of the base of the needle when the needle is in its working position (figure 5a).

14. [Claim 9] Purdy and Rossi teach the limitations of claim 1, upon which claim 9 depends. Purdy also teaches a catheter structure in which the blade (figure 5a, item 60) is suspended from the plate (figure 5a, item 64) of the cage.

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15. [Claim 10] Purdy and Rossi teach the limitations of claim 1, upon which claim 10 depends. In addition, Purdy discloses a catheter structure in which the needle (figure 5a, item 15) includes a base (figure 5a, item 64) bearing against the flexible blade (figure 5a, item 60) when the needle is in its working position.

16. [Claim 11] Purdy and Rossi teach the limitations of claim 1, upon which claim 11 depends. Purdy also teaches a short catheter which is adapted for insertion into a vein (figure 1a).

17. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Purdy et al. (patent number 5,215,528), in view of Rossi et al. (PGPub 2004/0243060), in further view of Woehr et al. (PGPub 2003/0195471).

18. [Claim 5] Purdy and Rossi teach the limitations of claim 1, upon which claim 5 depends. Additionally, Purdy discloses a flexible U-shaped blade, constituting a first rear transverse branch (figure 5a, item 60) located at the entrance of the chamber, which is equipped with a perforation (figure 5a, item 59) for the passage of the needle, as well as a second front transverse branch (figure 5a, item 63) parallel to the first branch, wherein the perforation of the rear transverse branch is not large enough to allow passage of the modified section of the needle (figure 5a, item 14c). Purdy and Rossi are silent on a second transverse branch which is equipped with a perforation for the passage of the needle. However, Woehr discloses an internal flexible catheter structure which has two parallel transverse branches, each with a perforation capable of allowing the passage of the needle through the catheter (figure 8). Purdy and Rossi are combinable with Woehr because they are both concerned with the same field of

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endeavor, namely catheters. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the structure taught by Purdy and Rossi with a perforation in the second transverse flexible branch taught by Woehr in order to provide an alternative means of preventing reuse of the needle.

19. [Claim 6] Purdy, Rossi, and Woehr teach the limitations of claim 5, upon which claim 6 depends. Purdy and Woehr are silent on a catheter base with an external rim, comprising a mobile lever and stop dog. However, Rossi discloses a catheter base with an external rim (figure 14, item 8), wherein the catheter cage includes a mobile lever and stop dog (figure 14, item 9) locked to this rim in one position of the lever. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the structure taught by Purdy, Rossi, and Woehr with the mobile lever and stop dog structure taught by Rossi in order to make the use of the catheter more efficient.

Response to Arguments

20. Applicant's arguments filed 1/29/2009 have been fully considered but they are not persuasive. Applicant's representative asserts that the prior art of record does not disclose the invention as claimed.

21. Examiner has fully considered the applicant's arguments but they are not persuasive. It is the examiner's position that given a careful reading, the claims do not distinguish over the prior art of record.

22. In regards to the rejection of claim 11 under 35 U.S.C. 112, applicant's representative has traversed the examiner's rejection of the use of the word "short" as indefinite. The examiner respectfully disagrees. The examiner asserts that the

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applicant has not provided any definition within the disclosure which distinctly and specifically defines the use of the term "short" or "short catheter," as stated in claim 11.

If the applicant wishes to rely on the document provided with the remarks/arguments received on 1/29/09, it should be noted that this should be in the form of a formal information disclosure statement. Furthermore, the specification would require an amendment to reflect this specific definition. In addition, it should be noted that the definition in the provided document refers to a "peripheral-short catheter," rather than a "short catheter," as claimed by the applicant.

23. With respect to claim 1, the examiner asserts that the prior art of record discloses the elements as claimed by the applicant. Applicant's representative asserts that the prior art (Purdy et al., USPN 5,215,528 and Rossi et al., PGPub 2004/0243060) fails to meet the limitations of claim 1. The examiner respectfully disagrees.

24. In response to applicant's argument that there is no suggestion of the combination of elements recited in claim 1, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

25. Furthermore, in response to applicant's argument that the prior art of record does not meet the limitations of claim 1, it should be noted that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed

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invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

26. With respect to claims 5 and 6, the examiner asserts that the prior art of record discloses the elements as claimed by the applicant. Applicant's representative asserts that the prior art (Purdy et al., USPN 5,215,528; Rossi et al., PGPub 2004/0243060; Woehr et al., PGPub 2003/0195471) fails to meet the limitations of claims 5 and 6. The examiner respectfully disagrees.

27. In response to applicant's argument that Woehr does not teach how to induce the displacement of the needle, it should be noted that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

28. The prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

Conclusion

29. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JASON FLICK whose telephone number is (571)270-7024. The examiner can normally be reached on Monday through Thursday, 7:00am to 5:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. F./
Examiner, Art Unit 3763
04/11/2009

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763